



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2657]

Advancing the Development of Pediatric Therapeutics 5: Advancing Pediatric Pharmacovigilance; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Division of Pediatric and Maternal Health, Office of Surveillance and Epidemiology, and Office of Pediatric Therapeutics, Food and Drug Administration (FDA or the Agency) are announcing a public workshop entitled "Advancing the Development of Pediatric Therapeutics 5: Advancing Pediatric Pharmacovigilance." The purpose of this 1-day workshop is to provide a forum to gather information on the latest developments in pediatric pharmacovigilance from the perspective of various stakeholders and to expand the conversation to include the utility and challenges of emerging pharmacovigilance tools, including specific challenges associated with pediatric data tools.

DATES: The public workshop will be held on Friday, September 14, 2018, from 8 a.m. to 5 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security

information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: For questions regarding the workshop, contact Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1732, denise.picabranco@fda.hhs.gov; or Meshaun Payne, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6668, meshaun.payne@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Drugs and biologics (products) receive marketing approval only after undergoing premarket review and upon establishment of safety and efficacy through adequate and well-controlled clinical trials. Because all safety issues related to a product may not be detected in the premarket phase, FDA receives and analyzes postmarket safety information to determine if events reported in the postmarketing period are likely to be related to exposure to a product. When FDA determines that reported postmarketing events are likely related to a product, FDA can introduce labeling changes and other activities to inform the professional and lay public.

FDA receives reports through the MedWatch website (<https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>), which are then entered into the FDA Adverse Event Reporting System for subsequent analysis. Because the volume of reports is large and because reporting entities (product manufacturers and the professional or lay public) need only suspect a possible link between product exposure and an adverse event, FDA

employs specific tools and strategies to assess postmarket safety reports and potential signals that arise from review of these reports. The process for receipt and assessment of such postmarket safety information is referred to as pharmacovigilance.

FDA has a specific regulatory mandate to perform pediatric pharmacovigilance and to present or make available the results of such pediatric pharmacovigilance to the Pediatric Advisory Committee.

II. Topics for Discussion at the Public Workshop

In this workshop, FDA will gather information on the latest developments in pediatric pharmacovigilance from the perspective of various stakeholders and expand the conversation to include the utility and challenges of emerging pharmacovigilance tools, including specific challenges associated with pediatric data tools.

III. Participation in the Public Workshop

Registration: Persons interested in attending this public workshop must register online at <https://www.eventbrite.com/e/advancing-the-development-of-pediatric-therapeutics-5-adept5-tickets-46654530958> by Thursday, September 6, 2018, midnight Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Onsite registration will not be available.

Registration for onsite participation or via webcast is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Denise Picabranco (denise.picabranco@fda.hhs.gov) or Meshaun Payne (meshaun.payne@fda.hhs.gov) no later than Thursday, September 6, 2018.

Streaming Webcast of the Public Workshop: Webcast information will be provided after participants have registered for the workshop. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Dated: July 27, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-16524 Filed: 8/1/2018 8:45 am; Publication Date: 8/2/2018]